

Information for Ambulance Services about Certificates of Compliance

What is the cost of a Certificate of Compliance?

A Certificate of Compliance is billed based on the annual test volume performed. The lowest cost is \$450 for up to 2000 tests per year.

How do I apply for a Certificate of Compliance in the state of Montana?

To apply for a Certificate of Compliance, you need to fill out a CMS-116 form, which can be downloaded from www.cms.gov/CLIA or at <http://dphhs.mt.gov/qad/Certification/CLIA>.

Once this form is complete and signed by the appointed qualified laboratory director, you may submit it to the State of Montana Department of Health and Human Services-Certification Bureau via FAX (406-444-3456), email (mtssad@mt.gov), or mail (Certification Bureau-2nd Floor, 2401 Colonial Drive, PO Box 202953, Helena, MT 59620-2953).

Please send the laboratory director qualifications with the application. This may include a diploma, transcript, resume, and proof of education. For more information on qualifications, see the <http://dphhs.mt.gov/qad/Certification/CLIA> for this information.

What address do I use on the application since my ambulance moves around from emergency to emergency?

Complete the “home base” address in the CMS-116 form on **page 1**. However, on **page 2**, check the “YES” Box under Multiple Sites. Under the three multiple site exceptions, select number 1, for **mobile units**. **Record the Vehicle Identification Number (VIN)** for each ambulance vehicle in this section, as directed. This will cover all testing in the ambulance as it moves to different locations away from the “home base”.

What if my information changes? (Ex. if the laboratory director quits, or you move to a new location)

The notification requirements for Certificates of Compliance are located at 42 CFR 493.51. The laboratory must notify the Certification Bureau (via fax, email, or mail listed above) of changes in name, location, and director within **30** days of the change. A written notice of these changes is required; verbal notification is not sufficient. Please include your CLIA number, name of facility, and the changes required for your CLIA certificate. Include your contact information in case we have further questions. If you are changing the laboratory director, please include the qualifications for the new director.

My ambulance is run by the hospital and I use the hospital’s CLIA number, do I still need to do this?

If you currently use a hospital CLIA number, you still need to notify us of that fact. You do not need to apply for a separate certificate. Currently, no ambulances are listed under hospital CLIA certificates in the State of Montana. The Vehicle Identification Number (VIN) still needs to be added to the hospital CLIA certificate information in order for the ambulance to be compliant with federal CLIA regulations.

How do I know if all my tests are classified as waived/moderate/or high by the FDA?

Look in the manufacturer instructions for the CLIA classification (waived, moderate, or high complexity). If it is not listed there, you may check one of two FDA websites to determine the complexity of your test:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm>

Links to these websites can also be found at: <http://dphhs.mt.gov/qad/Certification/CLIA>.

Who qualifies to be the laboratory director for a Certificate of Compliance?

The qualifications for a laboratory director of a Certificate of Compliance are found at 42 CFR 493.1405 for moderate complexity labs or at 42 CFR 493.1443 for high complexity labs. A separate document with this information is located at <http://dphhs.mt.gov/qad/Certification/CLIA>.

What are those regulations that apply to Certificates of Compliance?

The regulations for a Certificate of Compliance can be found at 42 CFR 493, all Subparts. For a copy, you may download it from www.cms.gov/CLIA.

I am a non-transport EMS service (ex. Fire departments, ski patrol, border patrol, quick response unit, sheriff office, and search and rescue department), does this apply to me?

If the service performs any laboratory tests, such as blood glucose with a glucometer, you need to have a CLIA certificate. If you do not perform any tests, then you do not need a certificate. The type of certificate (waiver vs compliance) is determined by the testing you perform.

I have a fixed wing/rotor wing ambulance service; does this apply to me or just to ground units?

If you perform any laboratory tests, such as blood glucose testing with a glucometer or blood gases, you need to have a CLIA certificate for your base location. The aircraft identification needs to be provided as a mobile testing site on the second page of the CMS-116 form.

I am a county-owned fast response unit, does this apply to me?

If you perform any laboratory tests, such as blood glucose with a glucometer, you need to have a CLIA certificate for your location. If you do not perform any testing, then you do not need a certificate. See the next question for combining county owned operations into one certificate to save money.

I am a county-owned service with another county-owned service based at the same location. Do we need 2 separate certificates (ex. County EMS and a County Fire Department)?

You may apply for 1 certificate if you have the *same tax ID and are a non-profit county owned provider*. On the second page of the CMS-116 application, check the “YES” box for the Multiple Sites section of the application. Under the three possible multiple site exceptions, select the #2 option of the “not-for-profit or Federal, State or local government laboratory engaged in limited (<15 tests total) public health testing.” List the information for the second provider in the boxes at the bottom of page 2 so that both sites are compliant with federal CLIA regulations.

I don't charge Medicare for this test, do I still need this?

Yes, if you perform any laboratory tests, such as blood glucose with a glucometer, regardless of how you bill for the services, you need to have a CLIA certificate for your location. Billing does not determine the need for a CLIA certificate. If you perform any laboratory services, you need to have a CLIA certificate.

What are the personnel licensure requirements to be a testing person for a Certificate of Compliance?

The testing personnel performing moderate or high complexity testing must qualify via education and experience in order to perform these tests. The exact qualifications can be found at 42 CFR 493.1421 (moderate testing) or at 42 CFR 493.1489. Please be aware of the qualifications for the clinical consultant (493.1417 or 493.1455), technical supervisor/consultant (493.1411 or 493.1449), and general supervisors (493.1461) are also based on education and experience. If you have further questions about who can qualify for these positions, please contact our office.

What about biennial surveys?

Certificates of Compliance undergo surveys to ensure compliance with the federal regulations every two years. The initial survey is performed approximately three months after the application has been processed. Biennial surveys are required for all Certificates of Compliance.

What happens if I don't do this?

Purposely **failing to comply** with this requirement may result in a termination of the Medicare/Medicaid provider agreement for the ambulance service. CMS makes the penalty determination, based on the information provided by this office.

Why do I need one of these certificates now? I have never had one in the past, what changed?

It has come to the attention of the Certification Bureau that ambulance services were not given the information concerning CLIA requirements.

Do other states have to do this or this just in Montana?

All states must comply with CLIA requirements.

What is all this I hear about glucometers and not using them on critically ill? Is this about that?

You may have heard about the FDA evaluating the use of glucometers in healthcare. This is a separate issue. This memo is correcting the lack of CLIA certificates for emergency medical providers using laboratory tests such as glucometers and blood gas analyzers without a CLIA certificate, which is in violation of the 42 CFR 493 federal regulations.

Who can I call to answer my questions?

For any further questions, please contact the Montana CLIA Program, Joyce Shepard at 406-444-2099. You may also email questions at mtssad@mt.gov. The Certification Bureau website also has information at <http://dphhs.mt.gov/qad/Certification/CLIA>.

